

Certificate of Analysis

Product name: Isoxsuprini hydrochloridum
Batch number / Weight: 19I20-B09-197406 / 10 G
Analysed according to: Ph. Eur.

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Identification B	Conform	Conform		
Identification E	White	Conform		
Appearance of solution	Clear Colourless	Conform		
pH	4,5 - 6,0	4,9		
Optical rotation	-0,05 - +0,05	+0,01	°	
Phenones	<=1,0	<1,0	%	
Related substances	<=2,0	Conform	%	
Loss on drying	<=0,5	0,2	%	
Sulphated ash	<=0,1	Conform	%	
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Isoxsuprine hydrochloride	99,0 - 101,0	100,8	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer

Analysis performed by the authorized lab.

Release:
Dominika Sołtysik
Qualified Person

22-04-2020

Expiration: 31-12-2023

Conclusion: APPROVED

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